

## REMARKS

With regard to Applicant's claim for foreign priority, Applicants respectfully submit that the certified translations have been requested and will be submitted under separate cover.

*Claims 18 – 27 stand rejected under 35 U.S.C. §112, first paragraph.*

The Examiner takes the position that the specification does not provide enablement for methods for evaluating responsiveness of an individual to any *in vivo* pharmaceutical by assaying for a thymine at position 825 or a thymine at position 1429 of SEQ ID NO: 1.

Applicants respectfully disagree and request that this rejection be withdrawn for the following reasons.

The test for enablement is whether one reasonably skilled in the art could make or use the invention, without undue experimentation, from the disclosure in the patent specification coupled with information known in the art at the time the patent application was filed. *U.S. v. Electronics Inc.*, 857 F.2d 778, 8 USPQ 2d 1217 (Fed. Cir. 1988).

Enablement is not precluded even if some experimentation such as routine screening is necessary. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986), cert denied, 480 U.S. 947. This is even so if the amount of experimentation required is laborious. *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). An invention meets the standard for successfully practice set by Section 112 unless the invention is "totally incapable of achieving a useful result." *Brooktree v. Advances Micro Devices*, 24 USPQ 2d 1401, 1412 (Fed. Cir. 1992).

Further, it is well established that compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, does not require the disclosure of a working example at all. An embodiment of the claimed invention can be based on predicted results rather than work actually conducted or results actually achieved. See *Gould v. Quigg*, 822 F.2d 1974, 1078; 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987). The specification need not contain an example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without

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an undue amount of experimentation. In re Borkowski, 422 F.2d 904, 908; 164 USPQ 642, 645 (CCPA 1970).

Claims 18 – 27, directed to a method for evaluating responsiveness of an individual to an *in vivo* pharmaceutical are fully enabled throughout the specification. In section one, starting at page 11 through section 14 at page 35, the application discusses the detail of the application of the present invention in prediction of diabetes mellitus (type II), adiposity/obesity, coronary heart disease and atherosclerosis, increased cholesterol, increased immune system function, increased t-lymphocyte, intensified progression of AIDS, osteoporosis, Alzheimer’s Disease, erectile dysfunction, thyroid gland dysfunctions, increased pregnancy risks and low birth rate.

Applicant submits that the teaching provided in these sections of the application and the knowledge and level of a reasonably skilled artisan would enable one to practice the claimed invention without undue experimentation.

In view of the above remarks, Applicant requests that this rejection, under 35 U.S.C. 112, first paragraph, be withdrawn.

*Claims 18 – 27 stand rejected under 35 U.S.C. §112, second paragraph.*

Applicant respectfully disagrees and request that this rejection be withdrawn for the following reasons.

Applicant respectfully submits that what is meant by “evaluating a genetic modification” would be clear to the skilled artisan especially in light of the present specification. Accordingly, Applicant respectfully request that this rejection be withdrawn.

*Claims 18 – 19 stand rejected under U.S.C. §102(a) as being anticipated by Naber et al.*

Applicant respectfully requests that this rejection be held in abeyance until the certified copies of the priority documents and certified translations are provided.

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*Claims 18 – 19 stand rejected under U.S.C. §102(a) as being anticipated by Zill et al.*

Applicants respectfully request that this rejection be held in abeyance until the certified copies of the priority documents and English language translations thereof are provided.

In view of the foregoing amendment it is respectfully submitted that all claims are in condition for allowance. Early and favorable action is requested.

If any additional fee is required, charge Deposit Account No. 50-0850.

Date: 9/24/03

Customer No.: 26770

Respectfully submitted,

  
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David S. Resnick (Reg. No. 34,235)  
NIXON PEABODY LLP  
101 Federal Street  
Boston, MA 02110  
(617) 345-6057